GENERAL INFORMED CONSENT

INFORMED CONSENT FOR CLINICAL RESEARCH

STUDY TITLE	Stress levels monitoring using sensor-derived signals from non-invasive wearable device and dataset development
INFORMED CONSENT FOR	Volunteer Participants
NAME OF RESEARCH INSTITUTION	Smart Sensors Lab and University Hospital Galway
NAME OF PRINCIPAL INVESTIGATORS	Prof. William Wijns; Dr Jane Walsh; Dr Gerard Molloy
NAME OF SPONSOR	Science Foundation Ireland
NAME OF INVESTIGATORS	Talha Iqbal; Dr Sandra Ganly; Dr Eileen Coen; and the research team
Participant ID	

This informed consent has two parts:

- INFORMATION SHEET
- CONSENT FORM

You will be given a copy of the full Informed Consent form for your records.

PART I: INFORMATION SHEET

INTRODUCTION

I am Talha Iqbal from Smart Sensors Lab. This research is on stress detection and monitoring using commercially available Empatica watches. I will give you information on this study and invite you to be part of this research. You do not have to decide today if you will participate. You may speak with anyone you wish before you decide if you want to participate. As we go through this information sheet, if there are words or terms you do not understand, please ask me and I will explain them to you. If you think of questions later, you can also ask them of me or anyone on the study.

PURPOSE OF THE RESEARCH

The purpose of this research is to prove the principle that stress can be monitored using photoplethysmogram (PPG) signals and how efficiently.

Objectives of the study:

- Monitor stress through PPG signal and determine its efficacy in a healthy population.
- Collect raw signal using the watch (wrist-worn device).
- Develop a dataset containing raw signals and labels (stress and non-stress).

Endpoints:

- Dataset of the healthy population to help to develop a new optimal device for accurate measurement of stress disorder.
- New classification technique for distinguishing stress from the non-stress condition.

TYPE OF RESEARCH INTERVENTION

You will be asked to perform three different time-constraint tasks with **6** min break in-between each task. Additionally, you will also be asked to fill out some questionnaires at the start and at the end of the experiment session. The overall study will take almost 45-60 minutes. At the commencement of the experiment, you will be informed of the order of phases, the duration of each phase, and what you require to do in each phase.

PARTICIPANT SELECTION

Inclusion criteria: To be eligible for study participation, the participant had to be (a) healthy with no kind of disease, (b) aged between 18 and 75 years, (c) able to complete both questionnaire and stress tasks in the English language, and (d) able to provide informed consent.

Exclusion criteria: Anyone with some issues interfering with giving informed consent, or previously had any underlying stress-related (triggering), the condition will be excluded. Moreover, breastfeeding mothers, pregnant women and colour-blind participants are also excluded.

VOLUNTARY PARTICIPATION

We ask you to participate in this study voluntarily. No Travel Allowance, Daily Allowance or any extra benefits will be given.

DESCRIPTION OF THE PROCESS

The developed study protocol is as follows:

1. You will arrive at the laboratory.
2. Sits for **5 min** and is asked whether they have any question/doubt about anything mentioned in the sent-out digital consent form. After answering all the questions, participant will be asked to sign the consent form (in hard form) if they agree to participate.
3. You will wear the watch on wrist.
4. Baseline readings (while sitting relax) will be recorded, and you will fill out the questionnaire: **10 MIN**.
5. Stroop Colour Word Task: **5 MIN**.
    - Name the ink colour, not the word
    - Do as many as possible but at least 200
    - Investigator can ask the participant to be quick (rush)
6. Rest + padding period (to bring back participant from stress) for **6 MIN.** (Rest + padding)
7. Trier Social Scale Test: **5 MIN.**
    - Talk about any stressful event that happened in their life.
8. Rest + padding period (to bring back participant from stress) for **6 MIN.** (Rest + padding)
9. Deep breaths and count the respiratory rate (hyperventilation test): **30-40 sec.**
    - Perform guided breathing.
10. Rest + padding period (to bring back participant from stress) for **6 MIN.** (Rest + padding)
11. Participant filling out the Perceived Stress Scale (PSS) and State-Trait Anxiety Inventory (STAI) questionnaire again for **5 MIN**.
12. Remove watch and close the session.

Note: The study only requires wearing a wrist-worn watch. There will be no blood collection, no needles, no pills, no medications. The study is completely non-invasive.

DURATION

The study will take **45-60 min** to complete.

RISK/SIDE EFFECTS

The task might induce some degree of stress. If you feel stressed even after the study, we will make sure that you get enough time to relax before starting a new task or going home. There will be nurses and a clinical team to ensure you feel relaxed during and at the end of the study.

BENEFITS

This study will help in getting the data required to develop a stress monitoring device with a highly intelligent algorithm to detect as well as predict stress. This will help in the betterment of the overall healthcare system as well as the device manufacturing industry.

RIGHT TO REFUSE OR WITHDRAW

Please reconfirm that participation is voluntary and you reserve the right to refuse or withdraw from the study at any stage. You will be able to do this by contacting Talha Iqbal at t.iqbal1@nuigalway.ie.

DATA CONFIDENTIALITY

The data will initially be stored on the watch. After completion of the session, the data from the watch will be transferred to the investigator's personal computer (secured with a password and only accessible to one person). The data collected will be allocated a unique identifier number and will be recorded as anonymous data.

The collected data will be stored in the personal computer of the investigator and will be password secured (only accessible to the investigator). The data will be anonymized and will be labelled by the participant ID.

DATA PROTECTION

1. The purpose or reason for processing their personal data.

We will be using your personal information in our research to prove the principle that stress can be monitored efficiently using photoplethysmogram (PPG) signals.

2. The legal basis under which you are processing their data.

The lawful basis is the valid legal reason to process and use data under GDPR. For this study the following two Articles from the General Data Protection regulation 2018 represent the legal basis for use of personal data:

- Article 6(1) (e): Processing is necessary for the performance of a task carried out in the public interest.
- Article 9(2) (j): Processing is necessary for scientific research purposes.

3. Who are the recipients of the data e.g., who will have access to the research participants' information?

All the information will solely be collected by the investigator and will not be shared with anyone before anonymization.

4. How long will the data be stored for and, if it is not possible to say, please give the criteria which will be used to determine that period.

The data will be kept stored for 5 years and will then be removed.

5. You should inform the data subject of any risks and/or implications that might arise for the data subject because of the data processing e.g., a data breach that could cause them harm.

We are going to collect raw photoplethysmogram PPG signal against the participant ID rather than any other identifier that might lead to the specific person. We will make sure that no data breach occurs but if it happens no harm will be caused to the participant.

6. That the data subjects have a right to withdraw consent. Please explain how they can go about doing this or what the withdrawal mechanism is.

The participant reserves the right to withdraw their consent at any stage of the study as well as after the study is concluded. To do so, the participant can contact *Talha Iqbal* at *t.iqbal1@nuigalway.ie*.

7. That the data subjects have a right to lodge a complaint with the Data Protection Commissioner.

We ensure that all the data will be used rightfully. If a participant thinks their data has been misused, they can ask Talha Iqbal at t.iqbal1@nuigalway.ie to delete their data. If they do not their confirmation email, they may complain to the Data Protection Commissioner.

8. That the data subjects have a right to request access to their data and a copy of it unless their request would make it impossible or make it very difficult to conduct the research.

The participants will have the right to access. This enables you to check what type of personal data we hold about you and what we do with that personal data and to receive a copy of this personal data.

9. That data subjects have a right to restrict or object to processing unless their request would make it impossible or make it very difficult to conduct the research e.g., the data subject doesn't want their data shared but doesn't mind having it collected and stored.

The participants will have the right to restrict or object to the processing of your data where that processing is carried out based on our legitimate interests. We will stop using your data unless we can demonstrate an overriding legitimate ground for the continued processing of this personal data.

10. That the data subjects have a right to have any inaccurate information about them corrected or deleted unless their request would make it impossible or make it very difficult to conduct the research.

The participants will have the right to rectification. This enables you to correct any inaccurate or incomplete personal data that we hold about you.

11. That the data subjects have a right to have their personal data deleted unless their request would make it impossible or make it very difficult to conduct the research. e.g., they wanted to delete their data at the end of a research project just before it is due to be published.

The participants will have the right to erasure their data. This enables you to request that we erase personal data held about you in certain circumstances.

12. That the data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.

The participants will have the right to data portability. This enables you to receive your data in a structured, commonly used, and machine-readable format and to have that personal data transmitted to another data controller.

13. Will there be automated decision making, including profiling? Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, to analyse or predict aspects of their performance at work, health or behaviour.

The data collected from all the participants will be processed and automated decision making about their stress/nonstress state will be predicted.

14. That the data subjects have a right to object to automated processing including profiling if they wish.

The participants will have the right to object to automated processing. This enables you to request that we erase the personal data that we hold about you.

15. You must inform the data subject if you intend to further process their personal data and provide the data subject with information on that other purpose.

All the participants will be informed beforehand if we intended to further use their data for any other purpose besides this study.

16. You must inform the data subject if you wish to transfer their data to a country outside of the EU or an international organisation and advise them of the safeguards you have in place to protect their data.

All the participants will be informed beforehand if we wished to transfer their data to a country outside of the EU or an international organisation and will advise them of the safeguards, we have in place to protect their data.

WHO TO CONTACT?

The designed study proposal, as well as protocol, has been approved by the hospital ethics committee. The study is completely safe and has no follow-up. If you agree and give consent for the participation in the study, please contact:

Name: Talha Iqbal

Email: t.iqbal1@nuigalway.ie

or

Name: Atif Shahzad

Email: atif.shahzad@nuigalway.ie

or

Name: Sandra Ganly

Email: sandra.ganly@nuigalway.ie

PART II: CERTIFICATE OF CONSENT

I, the undersigned, confirm that (please tick the box as appropriate):

1.	I have read and understood the information about the project, as provided in theInformation Sheet dated_____.	
2.	I have been allowed to ask questions about the project and myparticipation.	
3.	I voluntarily agree to participate in the project.	
4.	I understand I can withdraw at any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.	
5.	The procedures regarding confidentiality have been clearly explained (e.g. use ofnames, pseudonyms, anonymisation of data, etc.) to me.	
6.	If applicable, separate terms of consent for interviews, audio, video or other forms ofdata collection have been explained and provided to me.	
7.	The use of the data in research, publications, sharing and archiving has been explainedto me.	
8.	I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form.	
9.	I, along with the Researcher, agree to sign and date this informed consent form.	

STATEMENT OF CONSENT

I have read the study information, or it has been read to me. The risks of the procedure have been explained to me and are also identified in this documentation. Any questions I have about the intervention, its benefits, and its risks have been explained to my satisfaction. I give my informed consent to voluntarily participate in this research.

_____

Print Name of Participant

_____

Signature of Participant *Date*

STATEMENT BY THE RESEARCHER TAKING CONSENT

I have accurately read the information sheet to the potential participant and have ensured, to the best of my ability, that they understand the research study. I confirm that the participant was given adequate opportunity to ask questions about the study and I provided the answers to the best of my ability. I confirm that this individual has not been coerced into providing consent, and their consent has been given willingly and freely.

Print Name of Researcher

Signature of Researcher *Date*

A copy of this Informed Consent must be provided to the participant.